REMARKS

Claims 1-23 are currently pending in the application. Claims 1, 2, 4, and 5 are amended. Claims 24-27 are added. The new claims find support in the specification and are discussed in the relevant sections below. No new matter is added.

Formal Matters

The Office Action states that the IDS filed May 10, 2005 fails to comply with 37 C.F.R. §1.97(c) because it lacks the fee set forth in §1.17(p). Applicants respectfully point out that the May 10, 2005 IDS contained authorization to charge the fee for filing the IDS to Deposit Account 16-0085, reference number 8654/2222. A copy of the IDS is being filed herewith to confirm Applicants' authorization to charge the fee to the deposit account.

Applicants have also amended the specification to correct the claim for priority that was made when the instant application was originally filed. It has come to Applicants' attention that due to inadvertent error, and without deceptive intent, the instant application claimed priority as a **continuation** of PCT/GB02/04025, but should have claimed priority as a **continuation-in-part** of PCT/GB02/04025. Applicants request correction of the priority claim accordingly.

Rejection of Claims 1-23 Under 35 U.S.C. §102(b)

The Office Action has rejected claims 1-23 under 35 U.S.C. §102(b) as being allegedly anticipated by Siemann et al. (abstract) and Siemann et al. (Int. J. Cancer; "the Siemann et al. paper"). The Office Action asserted that the Siemann et al. abstract teaches "methods of treating sarcoma, breast, and ovarian tumors with a combination of DMXAA...and cisplatin or cyclophosphamide." The Office Action stated that the Siemann et al. abstract is being supplemented by the Siemann et al. paper, because the Siemann et al. paper allegedly teaches what is meant by a "rodent tumor model" as recited in the Siemann et al. abstract. The Office Action concludes that the Siemann et al. abstract thus teaches treating cancer by administering the claimed composition to a mammal.

Applicants acknowledge the ability of two or more references to be combined under certain circumstances to make a rejection under section 102. The facts of the case cited in the Office Action (Baxter Travenol Labs) is distinguished from the facts of the instant rejection, however. In Baxter, the primary prior art was a commercially available blood bag system that anticipated the claimed invention with the exception of the use of DEHP. Extrinsic evidence was provided to show that the commercial bags of the prior art would have contained DEHP. In the instant case, there is no evidence of record to support the contention that the teachings of the Siemann et al. paper describe the same experiments taught in the Siemann et al. abstract. Therefore, Applicants respectfully point out that it is not proper to combine the teachings of the two Siemann et al. references, because there is no indication that they are even describing the same experiments, and therefore, there is no evidence to support the Office Action's assertion as to what is meant by a "rodent tumor model" as recited by the Siemann et al. abstract. Moreover, even if it were assumed (which it is not) that the experiments taught in the Siemann et al. abstract relating to the use of DMXAA alone used the same tumor model as taught in the Siemann et al. paper, there is no teaching in the Siemann et al. abstract that the combination of DMXAA and cisplatin or cyclophosphamide was tested using the same tumor model. In fact, there is no teaching in the Siemann et al. abstract as to what assay was used to evaluate the drug combinations. Thus, the Siemann et al. abstract does not teach a method for treating cancer in a mammal by administering the claimed drug combinations *in vivo*. Applicants therefore request that the rejection be reconsidered and withdrawn.

Rejection of Claims 1-6 Under 35 U.S.C. §112, First Paragraph

The Office Action rejected claims 1-6 under 35 U.S.C. §112, first paragraph for alleged overbreadth. The Office Action asserts that while the specification is enabling for the treatment of a number of cancers, it does not "reasonably provide enablement for treating cancers in general." Applicants respectfully disagree and traverse the rejection.

Applicants have amended claims 1, 2, 4, and 5 to limit the claims from a method of treating cancer to a method for treating a "solid cancerous tumor." Support for this amendment is found on page 22, line 24 through page 23, line 2.

Unlike the assertions made in the Office Action, the claims are not directed to a method for using "one drug or one drug combination...[for] treating all cancers in general." The claims are drawn to a method of treating a solid cancerous tumor using a combination of DMXAA and an anticancer compound. One of skill in the art, given the disclosure of the instant specification and the level of knowledge and skill in the art, would be able to select a particular solid cancerous tumor of interest for treatment, select a particular anticancer agent from the list recited in the claims and known in the art to be useful for treatment of the particular selected tumor, use the anti-cancer compound in combination with DMXAA, and determine whether the solid cancerous tumor is treated by the chosen combination.

The specification teaches specific solid cancerous tumors that can be treated according to the claimed invention. The specification teaches at page 22, line 25 to page 23, line 2, that the invention can be used for treatment of solid tumors that can include such cancers as non-small cell lung cancers, small cell lung cancers, breast cancer, cancer of the pancreas, ovarian cancer, colorectal cancer, prostate cancer, gastric cancer, testicular cancer, bladder cancer, colonic carcinoma, parvocellular and non-parvocellular bronchial carcinoma, carcinomas of the cephalic and cervical parts, carcinomas of the thoracic and abdominal regions, cervical and endometrial carcinomas, sarcomas, and melanomas. In addition, the Examples provide specific teachings of the ability of the methods of the invention to treat mammary carcinoma using DMXAA in combination with each of vincristine (vinca alkaloid), carboplatin (platinum compound), cisplatin (platinum compound), cyclophosphamide, etoposide (topoisomerase II inhibitor), and doxorubicin (anthracycline); and pancreatic carcinoma using DMXAA in combination with gemcitabine (antimetabolite). In addition, the specification teaches dosage and administration ranges for each of the classes of anticancer compounds recited in the claims (pages 15 through 19). The specification also teaches how one of skill in the art, using no more than routine experimentation would test whether a specific combination of an anticancer compound and DMXAA is able to treat a particular solid tumor type. Page 23 teaches specific cell lines for use in an animal model that may be used to test the efficacy of particular drug combinations in treating over 20 different solid cancerous tumors.

The specification teaches that DMXAA has been shown to induce significant reduction in tumor blood flow (see page 1). It is well known in the art that solid tumors share the common feature of vascularization; a feature that may serve as a target for tumor treatment (See, e.g., Denekamp J. Endothelial cell proliferation as a novel approach to targeting tumour therapy. Br. J. Cancer, 45: 136-139, 1982.; Denekamp J. Review article: angiogenesis, neovascular proliferation and vascular pathophysiology as targets for cancer therapy. Br. J. Radiol., 66: 181-196, 1993.).

In further support of Applicants' contention that one of skill in the art would have been able to select a particular anticancer compound for use in combination with DMXAA for treatment of a particular solid tumor, the reference cited by the Office Action (Goodman & Gilmans's) teaches that conventional anti-cancer compounds (including those recited in the claims) can be used to predictably treat solid tumors including, but not limited to, neuroblastoma, breast tumor, ovarian tumor, lung tumor, Wilms' tumor, cervical tumors, testicular tumors, colon tumor, stomach tumors, pancreatic tumors, head and neck tumors, bladder tumors, small cell lung tumors, endometrial tumors, and thyroid tumors.

Thus, the specification teaches how to make and use the invention, and teaches further how one of skill in the art would test any combination of anti-cancer drugs encompassed by the instant claims for its ability to treat any type of solid cancerous tumor. As acknowledged by the Office Action, the level of skill of one in the art is high, thus the level of experimentation required to carry out the full scope of the claimed invention is merely routine, and not undue.

The Office Action asserts that the specification is not enabling because the "prior art recognizes that no one compound or combination of compounds is capable of treating" all cancers. The claims do not require that a single combination of compounds be able to treat all cancers. The claims relate to the treatment of a solid cancerous tumor by administering a combination of DMXAA and a known anti-cancer agent. The claims do not require that the selected anti-cancer agent in combination with DMXAA be able to treat all cancers. In addition, Applicants respectively submit that the assertion in the Office Action that "the prior art recognizes activity of the claimed compounds against a limited number of cancer types" is

misleading. As with this or any invention, it is the very fact that the prior art does not teach what is being claimed that makes the invention patentable. Moreover, the fact that a particular prior art reference reports on a particular combination of drugs recited in the claims relative to a particular cancer type (although, as noted above, Applicants do not concede that Siemann et al. teaches administration of the claimed combinations to a mammal to treat cancer) does not mean that the claimed compounds are "limited" to the treatment of just those types of cancers.

Taken together, the teachings of the specification and knowledge of those of ordinary skill in the art enable one of skill in the art to practice the full scope of the claimed invention without having to resort to undue experimentation. Applicants accordingly request that the rejection be reconsidered and withdrawn.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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